ANNEX

PART A

CHEMICAL ACTIVE SUBSTANCES

SECTION 1

Identity of the active substance

1.11. Analytical profile of batches

At least five representative batches from recent and current industrial scale production of the active substance shall be analysed for content of pure active substance, impurities, additives and each further component other than additives, as appropriate. All of the representative batches shall be within the last five years of manufacture. Where data from the last five years of production are not available, a justification shall be provided. The analytical results reported shall include quantitative data, in terms of g/kg content, for all components present in quantities of 1 g/kg or more and typically should account for at least 980 g/kg of the material analysed. For plant extracts and semiochemicals (such as pheromones), justified exemptions can be made. The statistical basis for the content proposed in the technical specification shall be explained (for example: maximum level found in practice, average plus three standard deviations of levels found in practice, etc.). Supporting data may be provided to further justify the technical specification. The actual content of components which are particularly undesirable because of their toxicological, ecotoxicological or environmental properties shall be determined and reported even if present in quantities below 1 g/kg. Data reported shall include the results of the analysis of individual samples and a summary of that data, to show the minimum, maximum and mean content of each relevant component.

Where an active substance is produced in different plants the information set out in the first paragraph shall be provided for each of the plants separately.

In addition, where relevant, samples of the active substance produced at laboratory scale or in pilot production systems, shall be analysed, if such material was used in generating toxicological or ecotoxicological data. If this data is not available a justification shall be provided.

Where the information provided relates to a pilot plant production system, the information required shall again be provided once industrial scale production methods and procedures have stabilised. Where available, industrial scale data shall be provided before approval under Regulation (EC) No 1107/2009. Where data on industrial scale production are not available, a justification shall be provided.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EU) No 283/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2019/556 reg. 21(4)
- Annex Pt. A s. 8 word omitted by S.I. 2019/556 reg. 21(5)(b)(xiv)
- Annex Pt. A s. 1 point 1.4 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(a)(i) by S.I. 2020/1567 Sch. 2 para. 61
- Annex Pt. A s. 1 point 1.4.1 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(b) by S.I. 2020/1567 Sch. 2 para. 61
- Annex Pt. B s. 9 words omitted by S.I. 2019/556 reg. 21(5)(c)(vi)
- Art. 1(1) Art. 1 renumbered as Art. 1(1) by S.I. 2019/556 reg. 21(2)(a)
- Art. 1(2) inserted by S.I. 2019/556 reg. 21(2)(b)